Huntleigh
HEALTHCARE

MAR 2 6 2002

K010744

510(k) SUMMARY
AC600 PUMP

Company	Huntleigh Healthcare Inc 40 Christopher Way Eatontown New Jersey
Contact	Audrey Witko Phone 732 578 9898 Fax 732 460 5809
Summary Preparation Date	19 Jan 2002
Trade Name	Flowtron Universal Model AC600 Pump
Common Name	Compression Limb Sleeve Device
Classification Name	Sleeve, Limb, Compression (JOW)

Predicate Devices

- Huntleigh FP5000 pump / FG100/200 Foot compression sleeves K965153
- Huntleigh Flowtron Excel Pump K961166
- Huntleigh DVT sleeves K881632
- Huntleigh DVT10(s) sleeves K9625717/A

Device Description

The AC600 Flowtron Universal is a pneumatic pump that supplies compressed air to inflate sleeves that are attached to a patient's limbs.

It has the same sleeve inflation characteristics as delivered by the predicate pumps, Huntleigh Healthcare FP5000 and Flowtron Excel.

It is designed to work with the existing ranges of Huntleigh Healthcare foot located and calf/thigh located sleeves.

The pump automatically senses the type if sleeve connected and adjusts the pressure/time cycle accordingly.

Each sleeve is compressed alternately, applying pressure to the patient's limb, principally to help prevent the formation of Deep Vein Thrombosis (DVT).

Intended Use

When used with DVT 10-40 calf/thigh garments (K961166).

- To help prevent Deep Vein Thrombosis (DVT)

When used with FG100-200 Foot Garments (K965153).

- To help prevent Deep Vein Thrombosis (DVT)
- Enhancement of venous & arterial circulation
- Prevention of venous stasis
- Assist healing of cutaneous ulcers
- Reduction of acute or chronic oedema
- Reduction of lower limb pain due to surgery or trauma
- Reduction of compartmental pressures

Summary of Technological Characteristics

Like the predicate devices, the AC600 pump comprises principally of an air compressor, and air distribution valve and a microprocessor based control system, all housed in a durable plastic casing.

The control system sets and monitors the air pressure cycle applied to the sleeves. It also monitors for faults caused by incorrect user set-up, sleeve failures, and pump system problems.

Automatic sleeve type recognition is achieved by sensing a specific value inductor, which is built into the sleeve hose connector.

Determination of Substantial Equivalence

The determination of substantial equivalence is based on non-clinical performance testing.

The AC600 pump has the same compressed air pressure/time profiles as the two predicate pumps, Flowtron Excel, and FP5000.

When used with the respective garments, it will give the same compressive force to the patient's limbs, hence the same therapy.

Indication of user and system faults is also identical to the predicate pumps.

Equivalence Testing Results

The respective ranges of predicate device sleeves were fitted to a person's limbs and the pressure/time profiles were recorded.

The inflation profiles of the AC600 pump were compared to the profile generated by the predicate pumps, Huntleigh Healthcare FP5000 and Flowtron Excel.

The key parameters of inflation time, inflation pressure and cycle time were determined to be identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

Mr. David M. Hampson
Technical Manager
Huntleigh Healthcare Inc.
40 Christopher Way
Eatontown, NJ 07724-3327

Re: K010744
Trade Name: Flowtron Universal, Model AC600
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve.
Regulatory Class: II
Product Code: JOW
Dated: February 6, 2002
Received: February 11, 2002

Dear Ms. Witko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

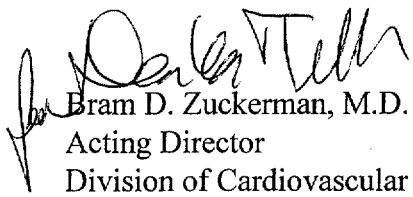
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

AC600 Pump

Ver/3 – 4/24/96

Applicant: Huntleigh Healthcare Inc.

510(k) Number (if known): K010744

Device Name: Flowtron Universal Model AC600 Pump

Indications For Use:

When used with DVT 10-40 calf/thigh garments (K961166)

- To help prevent Deep Vein Thrombosis (DVT)

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Division of Cardiovascular & Respiratory Devices
510(k) Number K010744

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)